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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,607	11/08/2001	Richard T. Lee	B0801.70231US00	6830
7590	06/30/2005			EXAMINER
Elizabeth Robin Plumer Wolf, Greenfield & Sacks, P.C. 600 Atlantic Ave. Boston, MA 02210			SITTON, JEHANNE SOUAYA	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,607	LEE, RICHARD T.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 November 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121 (It is noted that each group set forth below is subject to further restriction, see section 4 below):

- I. Claims 8-11, drawn to a method of diagnosing a cardiovascular conditions measuring aberrant expression using nucleic acids, classified in class 435, subclass 6.
- II. Claims 8-12, drawn to a method of diagnosing a cardiovascular condition by measuring aberrant expression using polypeptides and antibodies that bind the polypeptide, classified in class 435, subclass 7.1.
- III. Claims 13-15, and 26-36, drawn to kits or compositions comprising a nucleic acid or expression product of a nucleic acid listed in the claims, classified in class 536, subclass 23.1.
- IV. Claims 16-19, drawn to methods of treating a cardiovascular condition by administering an agent that modulates expression of a nucleic acid listed in the claims, classified in class 514, subclass 2.
- V. Claims 20-25, drawn to a method of screening for agents useful in treatment of a cardiovascular condition, classified in class 435, subclass 4.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I, II, IV, and V are patentably distinct from each because the methods have different effects, are not disclosed as capable of use together, and require different

reagents and method steps. The nucleic acid based diagnostic methods of group I require use of patentably distinct products, nucleic acids vs proteins/antibodies, than the diagnostic methods of group II. The treatment methods of group IV have different effects and different functions than the drug screening methods of group V. The methods further require different protocols drawn to different parameters and steps. The diagnostic methods of group I and II have different effects and reaction parameters, requiring different reagents, than the methods of treatment of group IV, and the drug screening methods of group V. The claimed methods are not required to be used together, nor are they obvious over one another. Accordingly, the methods of groups I, II, IV, and V represent independent and distinct inventions. The search burden for searching each of the patentably distinct groups represents a serious burden on the office as the searches are not coextensive in scope and as seen by their different classification. Art relating to diagnostic methods using nucleic acids will not necessarily have any information regarding diagnostic protein expression as expression of nucleic acids and proteins are not necessarily predictive of one another. Additionally, art relating to diagnostic methods will not necessarily have any information relating to treatment or screening for therapeutic agents, and vice versa.

The inventions of group III and I-II & IV-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the nucleic acids can be used to make fusion constructs to express proteins with enzymatic constructs which is not required to practice any of the methods of groups I-II or IV-V. Additionally, searching more than one of the patentably

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distinct groups represents a serious burden on the office because the searches are not coextensive, as exemplified by their different classification. Additionally, art providing structural information on the nucleic acid or expression product will not necessarily provide any information on diagnostic, treatment or drug screening methods, and vice versa.

3. Additionally, each group named above, as well as claims 1-7, is subject to further restriction. It is noted that the claims are drawn to examination of at least one of a number of different structurally and functionally distinct genes, in the alternative (claim 1), and in different combinations (claims 2-5). Applicant is required to further a specific combination of genes, either one or multiple genes. This is NOT an election of species. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, “[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.” 35 U.S.C. 121. Pursuant to this statute, the rules provide that “[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted.” 37 CFR 1.142 (a). See also 37 CFR 1.141(a). It is noted that searching more than one of the claimed patentably distinct sequences or combinations, represents a serious burden for the office.

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4. Claims (1-5), and 6-7 link, inventions in groups I and II. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims (1-5) and 6-7. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. Upon election of one specific or a specific combination of genes as set forth in section 3 above, specific claims from the group of claims 1-5 will be withdrawn from consideration as being drawn to non elected inventions. The remaining claim drawn to the elected single or combination will be examined along with claims 6 and 7 should either of groups I or II be elected.

5. Should applicant elect a single gene or specific combination of genes, and such single or combination is found to be allowable, applicant will be permitted to submit claims drawn to methods or products comprising the elected gene or elected combination, as well as other non elected genes, as long as the claims are limited to the elected gene or combination. It is noted that while the single or specific combination may be found to be allowable, claims drawn to

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combinations of such elected gene(s) as well as additional genes may raise issues under 35 USC 101, or 112, and subject to further rejection. Submission of such claims will be treated as set forth immediately below. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.**

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to

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retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and the search required group is different, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton

Jehanne Sitton
Primary Examiner
Art Unit 1634

6/27/05